

EFFECTIVE DATE

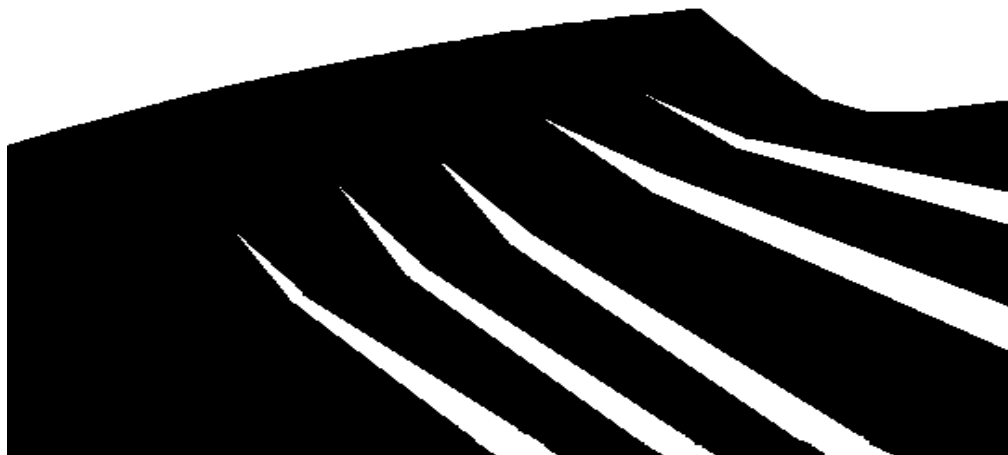
October 10, 1996

LANL-YMP-QP-06.3, R5

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PREPARATION, REVIEW, AND APPROVAL OF DETAILED TECHNICAL PROCEDURES

LOS ALAMOS ***QUALITY PROGRAM***



APPROVAL FOR RELEASE

M. J. CLEVINGER - PREPARER

Signature on file

DATE

M. J. CLEVINGER - QUALITY ASSURANCE PROJECT LEADER

Signature on file

DATE

J. A. CANEPA - TECHNICAL PROJECT OFFICER

Signature on file

DATE

Los Alamos
Yucca Mountain Site
Characterization Project

HISTORY OF REVISION

REVISION NO.	EFFECTIVE DATE	PAGES REVISED	REASON FOR CHANGE
R0	10/10/90	N/A	Initial procedure.
R1	01/31/94	All	Complete rewrite to streamline process and to incorporate QARD requirements.
R2	07/13/94	All	Revised to address RTN review comments.
R3	11/03/94	4, 6-8, Atts. 2 & 6	Revised to simplify record package requirements as identified in CAR YM-94-078, and to delete TPO signatures.
R4	06/03/96	All	Revised to address procedures in electronic media and to eliminate Document Control Coordinator responsibilities in this procedure.
R5	10/10/96	Attch. 2, Sec 6.0	Minor non-substantive editorial change to allow scientific investigation to continue while still providing tracking for method changes.

Los AlamosYucca Mountain Site
Characterization Project

PREPARATION, REVIEW, AND APPROVAL OF DETAILED TECHNICAL PROCEDURES

1.0 PURPOSE

This procedure describes the process to prepare, review, approve, revise, or delete a detailed technical procedure for the Los Alamos National Laboratory (Los Alamos) Yucca Mountain Site Characterization Project (YMP or Project).

2.0 SCOPE

- 2.1 This procedure governs all Los Alamos YMP detailed technical procedures.
- 2.2 This procedure applies to all Los Alamos YMP and Los Alamos-subcontractor YMP personnel (hereafter referred to as YMP personnel) who work under the Los Alamos YMP quality assurance program.

3.0 REFERENCES

LANL-YMP-QP-17.6, Records Management

4.0 DEFINITIONS

4.1 Deletion

Deletion of a procedure is the cancellation and removal of a procedure from the Los Alamos YMP document control system. Deleted procedures are not superseded.

4.2 Detailed Technical Procedure (DP)

A DP is a document that prescribes the methods used to conduct Los Alamos YMP technical activities that affect quality. A DP is used for repetitive work.

4.3 Revision

A revision is any change to the text or attachments of an existing procedure that results in an increment of the revision number of the procedure. Revisions follow the same review and approval process as a new procedure.

5.0 RESPONSIBILITIES

The following personnel are responsible for activities identified in Section 6.0 of this procedure.

- Quality Assurance Project Leader (QAPL)
- Principal Investigator (PI)
- YMP Personnel who initiate a DP action request
- DP preparer
- DP Quality Assurance (QA) Reviewer

6.0 PROCEDURE

The use of this procedure must be controlled as follows:

- If this procedure cannot be implemented as written, YMP personnel should notify appropriate supervision. If it is determined that a portion of the work cannot be accomplished as described in this QP, or would result in an undesirable situation, that portion of the work will be stopped and not resumed until this procedure is modified or replaced by a new document that reflects the current work practice.
- Employees may use copies of this procedure printed from the controlled document electronic file; however, employees are responsible for assuring that the correct revision of this procedure is used.
- When this procedure becomes obsolete or superseded, it must be destroyed or marked “superseded” to ensure that this document is not used to perform work .

6.1 Request for a New DP, DP Revision, or DP Deletion

NOTE: The DP Action Request is used to initiate and document the DP revision process. Any YMP personnel may submit a DP Action Request. In some cases, the PI may sign as the originator in Section I and as the PI in Section II.

6.1.1 **YMP Personnel** request a new DP, revision to an existing DP, or deletion of an existing DP by completing Section I of the DP Action Request (Attachment 1) as follows:

- 6.1.1.1 Check the action requested and provide a description of and reason for the proposed action.
- 6.1.1.2 To revise or delete an existing DP, enter the DP identifier, current revision number, and title. For a new DP, leave these spaces blank.
- 6.1.1.3 Print name, provide signature, and enter date in Section I and forward the form to the applicable PI.
- 6.1.1.4 If the YMP personnel requesting a new or revised DP is the applicable PI, it is not necessary to generate a DP Action Request. The PI proceeds to subsection 6.2.2.

6.1.2 After receiving the DP Action Request, the **PI** ensures that the information in Section I is complete and correct, reviews document history and determines whether the proposed action is warranted. The **PI** ensures that DPs are prepared and maintained as required to implement technical requirements.

NOTE: Most YMP work is described in study plans. These plans may contain lists of procedures that may need to be revised when new DPs, revisions or deletions of existing DPs occur.

- 6.1.3 If the action is warranted, the **PI** does the following:
- 6.1.3.1 Check the “approve” box in Section II of the DP Action Request.
 - 6.1.3.2 For a new DP, enter the assigned DP identifier, which is obtained from a document control representative, the revision level, which will be zero, and the title of the DP in Section I.
 - 6.1.3.3 For a new DP or revision of an existing DP, select and print preparer's name in Section II. For a DP deletion, check “N/A.”
 - 6.1.3.4 Print name, sign and date Section II. An information copy may be sent to the originator.
 - 6.1.3.5 If the request is for a new DP or a DP revision, proceed to subsection 6.2; if the request is to delete an existing DP, proceed to subsection 6.4.

OR

- 6.1.4 If the action is not warranted, the **PI** does the following:
- 6.1.4.1 Check the “do not approve” box in Section II of the DP Action Request and enter the reason for not approving.
 - 6.1.4.2 Enter “N/A” for the assigned preparer, sign and date Section II of the form.
 - 6.1.4.3 Send an information copy to the originator. No further action is required.

6.2 Preparation of a New DP or DP Revision

- 6.2.1 To initiate preparation of a new DP or revision of an existing DP, the **PI** forwards the DP Action Request and other pertinent background information to the preparer.
- 6.2.2 For creation of a new DP, the **preparer** prepares a draft of the DP in accordance with Attachment 2 and ensures that “DRAFT” appears on the DP.

OR

- 6.2.3 For revision of an existing DP, the **preparer** revises the DP in accordance with Attachment 2 and indicates changes in the procedure text by placing a vertical bar in the margin next to the changes; if changes are editorial, typographical, or affect the majority of the text of the procedure, change bars are unnecessary. The **preparer** ensures that “DRAFT” appears on the DP.

NOTE: Changes to the procedure, in addition to those requested on the DP Action Request, may be made by the preparer when the draft is prepared.

It is possible that changes approved by the PI on the DP Action Request may not be incorporated as a result of the DP review process.

6.3 Review and Approval of a New DP or DP Revision

6.3.1 To initiate a DP review, the **preparer** completes Section I of the DP Review Results (Attachment 3).

6.3.2 The **preparer** selects (the PI may help in the selection) a quality assurance representative to perform a quality assurance review and at least one reviewer who is technically competent in the subject area to perform a technical review.

The reviews must be performed by individuals other than the preparer. The reviews are conducted using the review criteria specified in DP Review Criteria (Attachment 5); however, supplemental review criteria may be added as appropriate.

6.3.3 If a technical reviewer is not YMP personnel (as defined in Section 2.0, SCOPE), the **preparer** processes a DP Reviewer Qualification (Attachment 6) as follows:

6.3.3.1 Complete the DP Reviewer Qualification and obtain the PI's printed name, signature and date. The PI's signature indicates approval of the qualification of the reviewer.

6.3.3.2 Forwards the DP Reviewer Qualification to a training representative as a Privileged Record in accordance with QP-17.6.

6.3.4 The **preparer** forwards to the reviewers, the DP Review Results (Attachment 3), the DP Review Sheet (Attachment 4), the DP Review Criteria (Attachment 5), the draft DP, and any pertinent background information.

6.3.5 After the reviewers return the review sheets, the **preparer** proceeds with the review process as follows:

6.3.5.1 Resolve review comments and document resolution of these comments on the DP Review Sheets. If the resolution of comments cause extensive changes to the draft DP and significantly change procedural implementation, repeat subsection 6.3 as appropriate.

6.3.5.2 Obtain (if applicable) reviewer's printed name, signature, and date in Section III of the DP Review Results.

6.3.5.3 Prepare a final version of the DP. Change bars are not required for the final version.

6.3.5.4 Sign and date the DP Title page (Attachment 7).

6.3.5.5 Obtain PI's signature on DP Title page.

6.3.5.6 Forward the DP to the QAPL as both hard & electronic copy.

- 6.3.6 The **QAPL** signs and dates the DP Title page and forwards a hard copy and an electronic copy (text only) of the final approved DP to a document control representative.
- 6.3.7 The **preparer** prepares a record package consisting of the records listed in subsection 7.1 and submits it in accordance with QP-17.6.

NOTE: The DP Review Criteria does not become part of the records package unless supplemental quality assurance review criteria are added.

6.4 Deletion of a DP

- 6.4.1 To delete a DP, the **PI** continues processing the DP Action Request prepared in subsection 6.1 as follows:
- 6.4.1.1 Complete Section II.
 - 6.4.1.2 Forward the DP Action Request to a document control representative.
 - 6.4.1.3 Prepare and submit, in accordance with QP-17.6, a record package consisting of the records listed in subsection 7.2.

7.0 RECORDS

The following records generated from this procedure are submitted as a record package. The DP Reviewer Qualification form is not submitted in the record package but is submitted, when appropriate, in accordance with subsection 6.3.3.

7.1 New or revised DP

- Draft DP
- DP Review Results
- DP Review Criteria (only if supplemental review criteria are added)
- Final approved DP
- Pertinent correspondence related to these documents

7.2 Deletion of DP

- DP Action Request
- Pertinent correspondence related to these documents

8.0 TRAINING REQUIREMENTS

- 8.1 Prior to conducting work described in Section 6.0, the QAPL, PI, QA reviewer and DP preparer require training to this procedure. Training to this procedure is accomplished by "read only."

- 8.2 YMP personnel (originators) who complete only Section I of the DP Action Request are indoctrinated to their duties during orientation training and are not required to train to this procedure. DP reviewers, (except for the quality assurance reviewer) are provided instructions on the appropriate forms and also do not require training.

9.0 ATTACHMENTS

- Attachment 1: DP Action Request (1 page)
- Attachment 2: DP Organization (5 pages)
- Attachment 3: DP Review Results (1 page)
- Attachment 4: DP Review Sheet (1 page)
- Attachment 5: DP Review Criteria (1 page)
- Attachment 6: DP Reviewer Qualification (1 page)
- Attachment 7: DP Title (1 page)
- Attachment 8: History of Revisions (1 page)

DP ACTION REQUEST

SECTION I. ACTION REQUESTED (Originator completes as appropriate)☐

NEW DP

☐

REVISE EXISTING DP

☐

DELETE EXISTING DP

DESCRIPTION OF, AND REASON FOR ACTION:

DP: _____
Identifier Revision Title

ORIGINATOR: _____
Print name Signature Date

RETURN THIS FORM TO THE APPLICABLE PI.

SECTION II. (PI approval and assignment)☐

APPROVE

☐

DO NOT APPROVE

☐

NA

REASON FOR DISAPPROVAL:

ASSIGNED PREPARER: _____ (☐ NA - for DP deletion)
Print name

PI: _____
Print name Signature Date

DP ORGANIZATION

- A. Each DP must contain, at a minimum, the following components: Title page, History of Revisions page, and sections that address purpose, scope, references, definitions, responsibilities, procedure, records, acceptance criteria, training requirements, and attachments (if any). Follow the criteria in this attachment to prepare a draft and final DP.

B. TITLE PAGE

The “DP Title” page (Attachment 7) provides a space for the effective date of the DP and spaces for signatures of the preparer, principal investigator and Quality Assurance Project Leader for approval for release.

C. HISTORY OF REVISIONS

The “History of Revisions” page (Attachment 8) includes all the revision numbers (beginning with 0), effective dates, brief descriptions of, and justifications for, the revisions, and, if applicable, information regarding superseded procedures.

NOTE: The effective date on the Title Page and the effective date on the History of Revisions page is entered by a document control representative.

D. HEADER BLOCK

Each page has a header that contains the DP number, revision, and pagination.

E. DP TITLE

The title indicates the primary activities conducted through the DP.

F. DP NUMBER

The DP number is a unique alphanumeric identifier configured as follows:

LANL-AAA-#-DP-xxx, Rn, where

- LANL indicates a Los Alamos YMP document
- AAA-# indicates a Los Alamos group designation and group number (previous or subsequent changes to this identifier, e.g., ESS to EES, do not constitute a new DP). The “#” is an optional additional identifier
- DP indicates a Detailed Technical Procedure
- xxx indicates the procedure's number
- R is an abbreviation for revision
- n is the DP revision number (0 indicates the initial DP)

Examples of DP identifiers are LANL-EES-13-DP-606, R1 and LANL-CST-DP-098, R0.

If the title of a procedure is changed, it is considered a new procedure and must receive a new number.

G. NOTES

Notes provide explanations or additional information and are entered into the text as follows:

NOTE: This is an example of how to insert a note into the text of a DP.

H. TEXT

The text of the DP follows a numerical, decimal, section -subsection format not to exceed three decimal points (e.g., 1.4.1.1). If an additional subsection is needed, it is prefixed with a lowercase alphabetical character (i.e., “a,” “b,” “c”). The following sections are required in all DPs.

1.0 PURPOSE

Describe the process the DP is designed to address.

2.0 SCOPE

Define the limits of application of the DP regarding affected activities and organizations (for clarity, specific exclusions may be stated). This section may also provide instructions for transition to the revised procedure.

3.0 REFERENCES

List the documents cited in Sections 4.0 thru 10.0.

4.0 DEFINITIONS

Provide definitions for terms specific to the DP. Consider using Quality Assurance Requirement Description (QARD) definitions and avoid redefining existing terms.

5.0 RESPONSIBILITIES

Identify, by YMP position title, (e.g., Quality Assurance Project Leader, Training Coordinator, etc.), the personnel responsible for implementing the activities described in Section 6.0, PROCEDURE, of the QP. If it is not practical to list specific YMP position titles, refer to individuals in general terms, (e.g., YMP personnel, quality assurance representative, etc.).

6.0 PROCEDURE

Provide clear, concise, step-by-step instructions that describe the technical requirements and state the activities to be performed and the person responsible for each activity (identify the responsible person by generic title or YMP position title). The preparer is responsible for determining the appropriate

level of detail. Address the subsections below as appropriate. In addition, the following information must be included at the beginning of Section 6.0:

The use of this procedure must be controlled as follows:

- If this procedure cannot be implemented as written, YMP personnel should notify appropriate supervision. If it is determined that a portion of the work cannot be accomplished as described in this DP, or would result in an undesirable situation, that portion of the work will be stopped and not resumed until this procedure is modified, replaced by a new document, or current work practice is documented in accordance with QP-03.5, subsection 6.1.6.
- Employees may use copies of this procedure printed from the controlled document electronic file; however, employees are responsible for assuring that the correct revision of this procedure is used.
- When this procedure becomes obsolete or superseded, it must be destroyed or marked “superseded” to ensure that this document is not used to perform work.

6.1 Principle

Provide a brief overview of the activity and explain how the DP relates to the overall scientific investigation.

6.2 Equipment and Hardware/Software

Identify the equipment used, including tools, gauges, instruments, standards, and computer hardware and software (data analysis software is described in subsection 6.6).

6.2.1 Equipment Malfunctions

Consider if a malfunction of equipment will be detectable during the collection or examination of data. If your ability to detect malfunctions is questionable, provide information on reducing the risk of such occurrences.

6.2.2 Safety Considerations

Identify any precautions, limits, and safety considerations.

6.2.3 Special Handling

Identify any special handling, storage, cleaning, packaging, shipping, and preservation requirements.

6.3 Preparatory Verification

Identify critical setup parameters, provide instruction to verify that prerequisites are completed, and list any mandatory verification points.

6.3.1 Hold Points

Checks of data and calculations may be considered hold points and are to be listed step by step, as appropriate.

6.3.2 Calibration

List any equipment or instrumentation that must be calibrated. All calibration activities are to be performed in accordance with QP-12.3. If calibration is not necessary, explain why. Measuring and test equipment notebook entries must reference unique identifier of measuring and test equipment.

6.3.3 Environmental conditions

Identify required controlled environmental conditions and describe how to verify that the conditions are met.

6.4 Control of Samples

Describe sample traceability. Identify sample preparation and any special sample handling, storage, cleaning, packaging, shipping, and preservation requirements. Sample activities are to be performed in accordance with QP-08.1.

6.5 Implementing Procedure

Provide a concise step-by-step description for implementing the DP. Describe methods for documenting work performed as required, such as providing forms for recording results, or by documenting required information (e.g., M&TE unique identifier) in a notebook.

6.6 Data Acquisition and Reduction

Identify the method(s) of data acquisition and reduction, including software to be used. Define parameters to be recorded and/or stored. Identify potential sources of uncertainty and error in data analysis activities that must be controlled and measured. Clearly define criteria for acceptance of the data, and note precision and accuracy needs.

NOTE: Acceptance criteria must be clearly stated, e.g., "Acceptance requires purity to be within 5% based upon a spectrophotometric scan and identified peaks."

6.7 Potential Sources of Error and Uncertainty

Include in the DP, criteria for recognizing and evaluating potential sources of error and uncertainty.

7.0 RECORDS

List the documents generated by the DP that are quality assurance records as defined in QP-17.6, and state whether the record is to be submitted to a Records Processing Center as a stand-alone record or as part of a record package.

NOTE: Reference manuals and their periodic updates can be entered into the YMP record system by implementing either QP-06.1 or QP-17.6.

8.0 ACCEPTANCE CRITERIA

Identify the acceptance criteria that show the procedure was correctly implemented.

9.0 TRAINING REQUIREMENTS

Specify the individuals listed in Section 5.0 who must be trained to the DP before performing the activities described in the DP. Identify the type of training required (e.g., read only or formal). Specify the individuals mentioned in the procedure who do not need to be trained to the DP and indicate why training is not required.

10.0 ATTACHMENTS

List each form or document identified in the DP as an “Attachment” using its attachment number, title, and number of pages as in the following example:

Attachment 1: Batch Columns Flow Chart (1 page)

ATTACHMENTS

Forms, figures, examples, and supplementary documents to the DP are included as attachments. Attachments are titled with the same titles as those listed in Section 10.0 of the DP. Attachments are numbered sequentially (i.e., “Attachment 1,” “Attachment 2”) and are placed in sequential order after the last page of the DP. Each attachment has its own pagination that is not included with the pagination of the DP (e.g., the first page of a three-page attachment would be labeled “Page 1 of 3”). Each attachment has a header that contains the DP number and revision, attachment number, and pagination in the upper corner, as in the following example:

<p>LANL-CST-DP-98, R0 Attachment 1 Page 1 of 2</p>
--

When a form is distributed as an attachment in an approved DP, the word “EXAMPLE” will appear on the form. Attachments that provide information (e.g., this attachment) should not be marked with the word “EXAMPLE.”

DP REVIEW RESULTS

Page 1 of 1

SECTION I. (Preparer completes)

DP IDENTIFIER: _____ REVISION: _____ TITLE: _____

PREPARER'S NAME: _____ PHONE: _____ MS: _____ DUE BY: _____
Print name

SECTION II. (Reviewer completes)

REVIEWER INSTRUCTIONS:

1. Review the DP against the attached Review Criteria.
2. For comments, enter the location of the section in question and the proposed actions on the attached review sheet. If "no comments," check the "No Comments" box and check the N/A box in Section III.
3. Any changes to original entries must be initialed and dated.
4. Complete Section II, return the review sheet(s) to the preparer identified in Section I.
5. After the procedure is modified, the reviewer completes Section III as appropriate.

I HAVE FOLLOWED THE INSTRUCTIONS FOR REVIEWING THIS DOCUMENT.

☐ Comments Attached

☐ No Comments

REVIEWER: _____
Print name Signature Phone Date

SECTION III. Signatures below indicate that all comments have been satisfactorily resolved.

☐ NA

REVIEWER: _____
Signature Date

AFTER COMPLETING SECTION III, RETURN REVIEW SHEETS TO THE PREPARER IDENTIFIED IN SECTION I.

LANL-YMP-QP-06.3

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LANL-YMP-QP-06.3, R5
Attachment 3
Page 1 of 1

DP REVIEW SHEET

Page ____ of ____

IDENTIFIER: _____ REVISION: _____ REVIEWER: _____

LOCATION

PROPOSED ACTION

RESOLUTION

EXAMPLE

LANL-YMP-QP-06.3

Los Alamos
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Characterization Project

DP REVIEW CRITERIA

CONSIDER THE CRITERIA BELOW, AS APPROPRIATE, AND DOCUMENT YOUR COMMENTS ON THE REVIEW SHEET.

SECTION I. TECHNICAL REVIEW CRITERIA

1. Are all the steps that are needed to perform this activity either listed or reasonably clear, correct and expected to be understood by a qualified individual?
2. Are the technical steps applicable, accurate, complete, adequate, clear and concise?
3. Are the acceptance criteria objective and capable of being adhered to?
4. Are sufficient records or data collected and recorded so that calculations or conclusions can be verified?
5. Are adequate calibration data and/or standards referenced?

SECTION II. QUALITY ASSURANCE REVIEW CRITERIA

1. Does the DP conform to the requirements listed in Attachment 2 of QP-06.3?
2. Is the DP capable of being implemented?

EXAMPLE

DP REVIEWER QUALIFICATION

NOTE: TO BE COMPLETED ONLY IF REVIEWER IS NOT A QUALIFIED MEMBER OF THE LOS ALAMOS YMP.

DOCUMENT TO BE REVIEWED:

PREPARER:

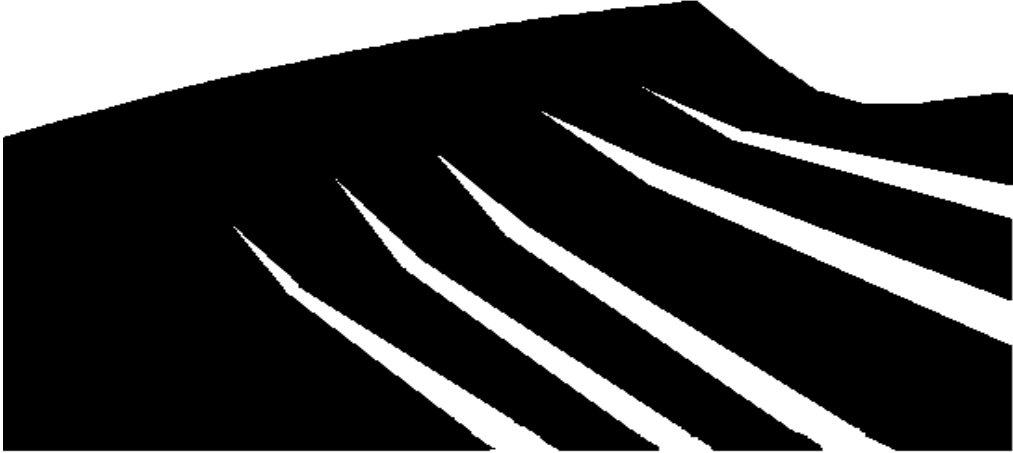
BRIEF DESCRIPTION OF CONTENT:

REVIEWER: _____
Print name Phone

SUMMARY OF REVIEWER'S QUALIFICATIONS:

OTHER COMMENTS: (Optional)

PI APPROVAL: _____
Print name Signature Date

EFFECTIVE DATE	LANL-AAA-#-DP-xxx, Rn Page 1 of
DP TITLE	
<p>LOS ALAMOS QUALITY PROGRAM</p> 	
APPROVAL FOR RELEASE	
NAME - PREPARER	DATE
NAME - PRINCIPAL INVESTIGATOR	DATE
NAME - QUALITY ASSURANCE PROJECT LEADER	DATE
<p>Los Alamos Yucca Mountain Site Characterization Project</p>	

LANL-AAA-#-DP-xxx, Rn

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HISTORY OF REVISIONS

REVISION NO.	EFFECTIVE DATE	PAGES REVISED	REASON FOR CHANGE
R0		N/A	Initial procedure
EXAMPLE			

Los Alamos
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